



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

28

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,879	07/28/2003	Michael M. Sekar	ABIOS.001A	3875
20995	7590	08/01/2006	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			YANG, NELSON C	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1641	

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,879

Applicant(s)

SEKAR ET AL.

Examiner

Nelson Yang

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/17/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claim 1 is acknowledged and has been entered.
2. Claims 1-21 are currently pending

Rejections Withdrawn

3. Applicant's arguments, see p.4, filed May 3, 2006, with respect to the rejection(s) of claim(s) 1-21 under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 9, 11, 12, 14, 15, 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al [US 6,544,776] in view of Tomei et al [US 5,037,207].

With respect to claim 1, Gold et al teach aptamers immobilized to the surface of biochips (column 10, lines 60-67), and measurement of fluorescence anisotropy to determine presence of target molecules (column 16, lines 15-36). Gold et al fail to specify how the aptamers are illuminated.

Tomei et al, however, teach a means of direct polarized illumination (fig. 4) for fluorescence anisotropy (column 7, lines 55-65). Tomei et al further teach that this means eliminates the need for mechanical translation stages for targets, and is capable of scanning targets of any size without gross stage movement (column 2, lines 21-30).

Therefore, it would have been obvious in the method of Gold et al to illuminate the aptamers with the illumination means of Tomei, in order to eliminate the need for mechanical translation stages for targets, and providing a illumination means capable of scanning targets of any size without gross stage movement.

1. With respect to claim 9, Gold et al teach the use of fluorescein (column 12, lines 16-20).
2. With respect to claims 11-12, Gold et al teach a 4x4 array of aptamers (fig. 1, column 3, lines 28-38).
3. With respect to claims 14, 15, Gold et al teach an array of photoreactive aptamers, where irradiation will covalently attach only the correct protein to the correct photoactivatable aptamer present at a defined area of a matrix laid out on the surface of the chip (column 18, lines 14-20), where multiple different probes may be used (column 14, lines 35-45).
4. With respect to claims 17, 18, 21, Gold et al teach that the attached nucleic acid ligands will bind to components of the blood plasma or other bodily fluid of an individual known to be suffering from a particular disease where the target molecules are not found in the bodily fluid of healthy individuals (col. 2, line 65 – col. 3, line 11).
5. With respect to claims 19-20, Gold et al teach that the target molecule can be a protein or metabolite (column 4, lines 45-58).

Art Unit: 1641

6. Claims 1, 8, 9, 11-13, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potyrailo et al [Potyrailo et al, Adapting selected nucleic acid ligands to biosensors, 1998, Anal Chem 70:3419-3425] in view of Tomei et al [US 5,037,207].

With respect to claims 1, 11, Potyrailo et al teach aptamers (p.3419, col.1) immobilized to a glass surface (p.3420, col.1) and the use of fluorescence anisotropy to detect the bound labeled aptamer probe-analyte binding event using a vertically polarized laser (p.3420, col.2). Potyrailo et al fail to teach the direct illumination of the aptamers with polarized light.

Tomei et al, however, teach a means of direct polarized illumination (fig. 4) for fluorescence anisotropy (column 7, lines 55-65). Tomei et al further teach that this means eliminates the need for mechanical translation stages for targets, and is capable of scanning targets of any size without gross stage movement (column 2, lines 21-30).

Therefore, it would have been obvious in the method of Potyrailo et al to illuminate the aptamers with the illumination means of Tomei, in order to eliminate the need for mechanical translation stages for targets, and providing a illumination means capable of scanning targets of any size without gross stage movement.

It should be noted that although Potyrailo et al specifies that evanescent wave is more advantageous than direct sample illumination, Potyrailo et al do not preclude the use of direct sample illumination (p.3422, col.2, lines 37-43).

6. With respect to claim 8, the aptamers comprise 15-mer single-stranded DNA that bind to the blood-clotting factor thrombin (p.3421, col.2).

7. With respect to claim 9, Potyrailo et al teach the use of fluorescein isothiocyanate (p. 3419, col.2).

Art Unit: 1641

8. With respect to claims 12, 13, since Potyrailo et al teach multiple anti-thrombin DNA aptamers (p.3419, col.1) immobilized to a glass surface (p.3420, col.1), each aptamer could be considered a single addressable location (fig.1).

9. With respect to claim 16, a vertically polarized laser is used to detect fluorescence anisotropy (p.3420, col.2).

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al [US 6,544,776] in view of Tomei et al [US 5,037,207] and further in view of Wei et al [US 6,576,419].

With respect to claim 10, Gold et al teach aptamers immobilized to the surface of biochips (column 10, lines 60-67), and measurement of fluorescence anisotropy to determine presence of target molecules (column 16, lines 15-36), as discussed above. Gold et al and Tomei et al fail to teach the use of carboxyfluorescein instead of fluorescein (column 12, lines 16-20) to label the aptamer.

Wei et al, however, teach the use of fluorescein and carboxy fluorescein (column 15, example VI), showing that they are equivalent structures known in the art.

Therefore, because these two were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute carboxyfluorescein for fluorescein in the method of Gold et al and Tomei et al, as suggested by Wei et al.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Potyrailo et al [Potyrailo et al, Adapting selected nucleic acid ligands to biosensors, 1998, Anal Chem 70:3419-3425] in view of Tomei et al [US 5,037,207] and further in view of Wei et al [US 6,576,419].

Art Unit: 1641

With respect to claim 10, Potyrailo et al teach anti-thrombin DNA aptamers (p.3419, col.1) immobilized to a glass surface (p.3420, col.1) and the use of fluorescence anisotropy to detect the bound labeled aptamer probe-analyte binding event using a vertically polarized laser (p.3420, col.2). Potyrailo et al and Tomei et al fail to teach the use of carboxyfluorescein instead of fluorescein (column 12, lines 16-20) to label the aptamer.

Wei et al, however, teach the use of fluorescein and carboxy fluorescein (column 15, example VI), showing that they are equivalent structures known in the art.

Therefore, because these two were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute carboxyfluorescein for fluorescein in the method of Potyrailo et al and Tomei et al, as suggested by Wei et al.

Response to Arguments

9. Applicant's arguments filed May 6, 2006 have been fully considered but they are not persuasive.

10. In particular, applicant argues in essence that fluorescence anisotropy is a broad field, and that one of ordinary skill in the art would not have expected that direct illumination would work in a system wherein the fluorophore was bound to the support (via an aptamer) and not to the analyte. Applicant further argues that the techniques taught in the prior art emphasized noise reduction and signal sensitivity as important for the methods. In essence, it is believed that applicants are arguing unexpected results, as at the time of the invention, one skilled in the would have believed that changes in anisotropy due to the binding of an analyte to an aptamer that was already attached to a substrate would not have been detectable through a direct illumination

Art Unit: 1641

technique. While the Office notes these arguments, it is not entirely clear that this was the original focus of the invention. In particular, support for direct illumination could only be found in pg. 0047 of the specification, wherein applicants discuss focusing polarized light on a desired area. Furthermore, there is no mention or comparison of the techniques used to illuminate the sample (i.e. comparison of non-direct vs. direct), or that the use of direct illumination produced unexpected results. Therefore, since Tomei does disclose motivation for providing direct polarized illumination, there would have been a reasonable expectation of success of using direct polarized illumination in the methods of Potyrailo et al and Gold et al. It should be noted that even though Potyrailo et al teaches advantages of using evanescent light instead direct, Potyrailo et al does not teach that direct illumination would not work, and therefore, one of ordinary skill in the art would have expected that direct illumination would have had some amount of success.

11. However, applicant may wish to provide an affidavit which provides evidence which would teach that one of ordinary skill in the art at the time of the invention would not have expected the invention as claimed to work, or if applicant has data which demonstrates that direct illumination performs **unexpectedly** better than what was expected at the time of the invention, applicant may also wish to include this in the affidavit. The Office believes that this would greatly aid in advancing prosecution, and help support applicant's arguments regarding the rejections.

Allowable Subject Matter

Art Unit: 1641

12. Claims 2-7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion


13. No claims allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641


LONG V. LE 07/24/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600